DEC - 6 2000

510(k) Summary of Safety and Effectiveness
Influent Ltd.'s SleepStrip
510(k) Number K002135

Influent Ltd., 3 Hasadnaot Street, Herzliya, 46728, Israel submitted this 510(k) notice for the SleepStrip. The contact person is Jonathan S. Kahan, Esq., Hogan and Hartson, LLP, 555 Thirteenth Street, N.W. Washington, DC 20004. His phone number is (202) 637-5794. His facsimile number is (202) 637-5910.

Intended Use/Indications

The SleepStrip is intended for use in monitoring nasal and oral airflow. The device is indicated for use as a prescreening tool to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.

Comparison to the Predicate Devices

The *SleepStrip* is substantially equivalent to EPM Information Systems, Inc.'s Easyflow cleared under K922112. The technology and intended use are substantially equivalent. The *SleepStrip* is substantially equivalent to the Ultima airflow sensor cleared under K981445 with respect to intended use and indications. The *SleepStrip* has several minor differences with respect to its predicate devices:

1. The *SleepStrip* uses a miniature processing unit to log, analyze and display the data on itself, while both predicates use data recorders for acquisition and analysis.
2. The *SleepStrip* uses non-volatile display elements for presenting the study output to the patient or health-care provider, in contrast to the predicates, which present their data through the recorder.
3. The *SleepStrip* is activated by pulling a "Pullout" tab, while the other devices are passive, and start collecting data upon beginning a recording process.

Based on the information provided, the *SleepStrip* is substantially equivalent to the Easyflow and to the Ultima airflow sensor devices with respect to intended use, technological characteristics, and performance.

Summary of Clinical Test Results

A comparative test that examined the SleepStrip results vs. a conventional sleep lab PSG was performed on 196 patients at three sleep laboratories. Patients were included in the test if they were suspected of suffering from sleep

apnea syndrome. Patients were excluded from the test if they suffered from congested nose, or any other respiratory tract condition. Patients were tested for at least five hours after the twenty-minute calibration period.

The patients were interviewed by a laboratory physician. They completed sleep questionnaires. Physical measurements of the patient's height and weight were used to calculate his or her body mass index. PSG was conducted simultaneously with the patient's use of the SleepStrip.

When the overall correlation between the Sscore and AHI was calculated (based on the comparison made between the SleepStrip results and the average AHI as determined by PSG monitoring in each of the participating laboratories), the overall correlation coefficient between the Sscore and AHI was 0.71.

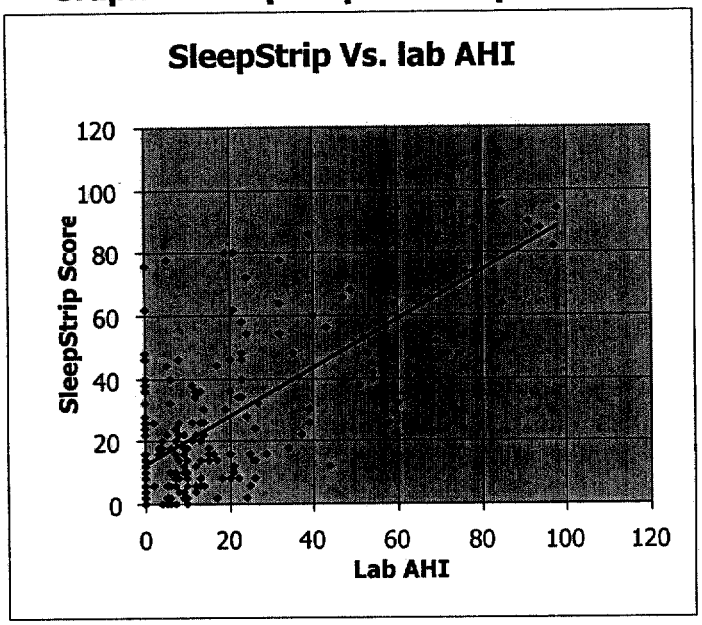
Calculation of sensitivity and specificity of the SleepStrip for a single, constant SleepStrip threshold, set at 20, resulted in different sensitivities and specificities for different AHI levels as shown in the following table and graph:

Table 1. Sensitivity and specificity for different PSG results with SleepStrip threshold set at Sscore=20 (N=196)

	Entire Population	
AHI	**Sensitivity**	**Specificity**
20	0.82	0.66
30	0.95	0.62
40	0.97	0.59

The sensitivity of the SleepStrip increased for higher AHI levels with only a minor decrease in specificity. The results show that the probability of getting a false negative result with the SleepStrip in case of moderate (AHI>30) or severe (AHI>40) sleep apnea is very small.

Graph 1. SleepStrip vs. Sleep Lab AHI



Summary of Comparison to Other Devices that Automatically Record Data Used to Screen for or Diagnose Sleep Apnea

Mesam IV recorder, which was cleared for marketing by FDA on June 8, 1990 under K901466 (Regulation No. 868.2375; Product Code BZQ, Monitor, Breathing Frequency). This device can be used at sleep lab or at home. According to the manufacturer, the device records a total of four parameters: intermittent snoring index ("ISI"), heart rate ("HVI"), oxygen saturation ("ODI") and body position. The parameters that are the most relevant for a comparison to the SleepStrip are ISI and ODI because they are directly related to breathing. Analysis of the results may be performed automatically or by hand scoring.

Several scientific articles were published that analyze the device sensitivity and specificity regarding automatic scoring vs. PSG. The following table summarizes the results:

Authors	Journal	Cut-off Value	Sensitivity	Specificity
Stoohs and Guilleminault	Chest (1992); 101: 1221-7	=10	HVI: .58 ISI: .96 ODI: .92	.32 .27 .97
Duran Cantolla et al.	Arch. Bronconeumol. (1994); 30:331-8	=10	HVI: .59 ISI: .84 ODI: .94	.58 .26 .26
Koziej et al.	Eur. Respir. J. (1994); 7: 1771-5	=10	HVI: .81 ISI: .92 ODI: 1.00	.74 .16 .27

These parameters were not combined and as such, provide specificity and sensitivity of each one of the indices.

The ResMed Autoset devices were cleared for marketing by FDA under K970771, K980721 and K984428 as nasal CPAP systems with product code 73 BZD. This device may be used both at home or at sleep labs. These systems have diagnostic capabilities, validated in the scientific articles, the results of which are summarized in the following table. When in diagnostic mode, the Autoset measures Oxygen saturation, Apnea duration, Respiratory effort, Nasal ventilation, Heart rate, Body position, Snore index and Flattening index (flow limitation).

Authors	Journal	Cut-off Value	Sensitivity	Specificity
Gugger	Eur. Respir. J. (1997); 10: 587-91	=20	.97	.77
Fleury et al.	Sleep (1996); 19: 502-5	=20	1.00	.88
Gugger et al.	Thorax (1995); 50: 1199-201	=20	.82	.90

The SleepStrip uses 3 thermistors to measure nasal and oral airflow. The results for a cut-off Sscore of 10 or more are calculated from the results submitted in the 510(k) submission.

Authors	Journal	Cut-off Value	Sensitivity	Specificity
Lavie et al.	Sleep (2000); 23 (Suppl. 2): A7.	=20	.82 - .97 (Sensitivity values increased for higher AHI thresholds)	.66 – .59 (Specificity values decreased for higher AHI thresholds)

Conclusion

Given that both predicate devices use larger number of measurement channels, while the SleepStrip uses only one channel, and based on the above mentioned results, for both cut-off AHI values and Sscores of 10 and/or 20, the SleepStrip has a sensitivity that is comparable to both the ResMed Autoset and the Oxygen Saturation component ("ODI") of the Mesam IV system. The SleepStrip has better sensitivity (the ability to identify patients with Sleep Apnea) than the Heart-rate Variation Index ("HVI") and/or the Intermittent Snoring Index ("ISI") of the Mesam IV.

The specificity of the SleepStrip is comparable to that of the Mesam IV and somewhat lower than the Autoset. Again, taking into consideration the more varied array of evaluation channels of the two predicate devices, the difference in specificity is low.

In conclusion, the SleepStrip is a simple and user-friendly device with specificity and sensitivity that are comparable to the Mesam IV and Autoset predicate devices. The SleepStrip is indicated for use as a prescreening tool while the Mesam IV and the AutoSet are indicated for diagnosing sleep apnea. Therefore, the SleepStrip is substantially equivalent to these devices for its indication even if, based on some reports, its sensitivity and specificity is slightly lower than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. Jonathan S. Kahan
Influent Ltd.
c/o Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K002135
SleepStrip
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: October 24, 2000
Received: October 25, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: *SleepStrip*

Indications for Use: The SleepStrip is intended for use in monitoring nasal and oral airflow. It is generally indicated for use by physicians to screen patients to determine the need for further clinical evaluation by polysomnography based on their SleepStrip score ("Sscore"). SleepStrip is specifically indicated to obtain a quantitative measure of respiratory airflow, which correlates with the Apnea Hypopnea Index ("AHI"). SleepStrip is intended for use with adult users during an overnight sleep, i.e., less than 24-h.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)

510(k) Number K002135

Division of Cardiovascular & Respiratory Devices
510(k) Number K002135

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use_____